## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ecoporc SHIGA suspension for injection for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

**Active substance:**

*Escherichia coli*, recombinant Shiga toxin 2e: $\geq 3.2 \times 10^6$ ELISA units

**Adjuvant:**

Aluminium (as hydroxide) max. 3.5 mg

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Thiomersal | max 0.115 mg |
| Water for injections | |

Appearance after shaking: yellowish to brownish, homogenous suspension.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs

### 3.2 Indications for use for each target species

Active immunisation of piglets from the age of 4 days, to reduce the mortality and clinical signs of oedema disease caused by Stx2e toxin produced by *E. coli* (STEC).

Onset of immunity: 3 weeks after vaccination
Duration of immunity: 15 weeks after vaccination

### 3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to the adjuvant or to any of the excipients.

### 3.4 Special warnings

Vaccinate healthy animals only.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

## 3.6 Adverse events

Pig:

| | |
|---|---|
| Common<br>(1 to 10 animals / 100 animals treated): | Injection site swelling[1]<br>Elevated temperature[2] |
| Uncommon<br>(1 to 10 animals / 1,000 animals treated): | Behavioural disorder[3] |

[1] Small local reaction (maximum of 5 mm), subsiding within a short time (up to seven days) without treatment.
[2] A slight rise in body temperature (maximum of 1.7 °C), subsiding within a short time (maximum of two days) without treatment.
[3] Temporary mild behavioural disturbances.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

## 3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
The use is not recommended during pregnancy and lactation.

## 3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

## 3.9 Administration routes and dosage

Intramuscular use. The preferred application site is the neck muscle behind the ear. It is recommended to use a needle appropriate for the age of the piglets (preferred size 21G length 16 mm).

Prior to administration, shake the vaccine carefully.

A single intramuscular injection (1 ml) to pigs from the age of 4 days.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Following the administration of a double dose of vaccine no adverse reactions other than those described in section 3.6 have been observed.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

### 3.12 Withdrawal periods

Zero days.

## 4. IMMUNOLOGICAL INFORMATION

### 4.1 ATCvet code: QI09AB02

Immunologicals for suidae, inactivated bacterial vaccines.

The vaccine consisting of *Escherichia coli*, recombinant Shiga toxin 2estimulates an active immunity against Shiga toxin 2e produced by the causative agent of oedema disease in pigs.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 24 hours
Between the withdrawals, the vaccine should be stored at 2 °C – 8 °C.

### 5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

### 5.4 Nature and composition of immediate packaging

PET bottle containing 50 ml or 100 ml closed with a bromobutyl rubber stopper and sealed with an aluminium tear-off cap.

Pack sizes:
Cardboard box with 1 PET bottle of 50 doses (50 ml) or 100 doses (100 ml).

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Ceva Santé Animale

## 7. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/149/001
EU/2/13/149/002

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 10/04/2013

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).